Remarks

Claims 1, 4-8, 11-18, 20, 24-31 and 33 are pending. Claims 1, 4 and 20 have been amended. Claims 3 and 19 have been canceled. Claims 5, 7, 8, 13-15 and 24 have been withdrawn from consideration as being drawn to a non-elected invention. Claim 1 has been amended to further include the limitation of claim 3. Claim 4 has been amended to correct dependency from canceled claim 3. Claim 20 has been amended to correct dependency from canceled claim 19. No new subject matter has been added.

Election of Species

Claims 5, 7, 8, 13-15, and 24 were withdrawn as drawn to a non-elected species. These claims are still pending, and fall within the generic claim 1. Accordingly, once claim 1 is determined to be allowable, all of claims 5, 7, 8, 13-15 and 24 should also be examined.

Rejection Under 35 U.S.C. § 102

Claims 1, 6, 11, 12, 16, 25 and 33 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,741,329 to Agrawal et al. ("Agrawal"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Agrawal

Agrawal describes a pH-controlling device formed of a biodegradable *porous* polymer and a pH-controlling substance or buffering agent (col. 2, lines 6-42; col. 8, lines 17-28; abstract). The biodegradable polymer can be polyglycolic acid, polylactic acid, and poly(glycolic acid-co-lactic acid) (col. 3, lines 50-59). The pH buffering agent or pH-controlling

agent can be calcium carbonate, sodium bicarbonate, calcium hydroxyapatite, or a mixture thereof (col. 4, lines 23-26) in the amount of about 1% to 99% by weight or 5% to 30% by volume of the polymer (col. 4, lines 31-33). The implantable device may be in the form of a pin, screw, staple, nail, suture or fiber (col. 4, lines 53-60).

The claims are drawn to a resorbable interbody spinal fusion device. Claim 1 has been amended to more clearly state that the device is an interbody spinal fusion device in the body of the claim as well as in the preamble.

Agrawal does not describe or suggest an interbody spinal fusion device. Accordingly, Agrawal does not disclose the claimd subject matter.

Rejection Under 35 U.S.C. § 103

Claims 1, 3, 6, 11, 12, 16, 25, 30 and 33 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,961,740 to Ray et al. ("Ray"), in view of Agrawal. Claim 4 was rejected under 35 U.S.C. § 103(a) as obvious over Ray in view of Agrawal, and further in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan). Claims 17-20 were rejected under 35 U.S.C. § 103(a) as obvious over Ray in view of Agrawal, and further in view of U.S. Patent No. 4,655,777 to Dunn et al. ("Dunn"). Claims 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as obvious over Ray in view of Agrawal, and further in view of U.S. Patent No. 5,527,864 to Suggs et al. ("Suggs"). Applicants respectfully traverse these rejections to the extent that they are applied to the claims as amended.

Ray

Claims 1, 3, 6, 11, 12, 16, 25, 30 and 33 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,961,740 to Ray et al., in view of Agrawal.

Ray describes an interbody fusion cage formed of stainless steel, titanium, ceramics, or a super-strength polymer or composites such as super-high-density polyethylene, glass, or graphite (col. 4, lines 31-35). The polymer can be biodegradable (col. 4, line 39) but is not defined as being porous. The fusion cage has a threaded outer surface and an internal cavity which is adapted to be filled with bone chips (col. 3, lines 39-41). Ray does not describe using up to 75% of a pH-neutralizing agent or buffering agent to form the interbody fusion cage, though it states that hydroxyapatite can be used as a bone activating matter placed in the cavity of the cage (col. 4, lines 46-48).

There is no suggestion in either Ray or Agrawal to combine the references. Agrawal describes implantable devices made from *porous, biodegradable* polymers such as PLA, PLGA, and copolymers thereof. Ray clearly is not directed to polymers of this structurally-weakened nature. While Ray makes mention that the fusion cage may be made of a biodegradable polymer, he focuses on metal and ceramic materials for the formation of the cage, stating that stainless steel is the preferred embodiment (col. 4, lines 30-45). To the extent that he even mentions polymers, he stresses the need for *super-strength* polymer characteristics, as found in polyethylene, glass, or graphite, none of which are biodegradable.

The implantable device as described by Agrawal at col. 4, lines 1-34, is formed of a polymer in combination with sodium bicarbonate as an alkaline agent of choice in a amount of 1% to 99% by weight or 5% to 50% by volume of the polymer used. Sodium bicarbonate is highly water soluble and has no mechanical strength when placed in water. It is counterintuitive to construct a fusion cage with a *large internal cavity* from a material comprised of a porous, biodegradable polymer comprised of up to 99% soluble buffering agent. Therefore there is no reason to combine Ray with Agrawal, nor any reasonable expectation of success in the combination of the describeings. Applicants have described a means for producing a viable resorbable interbody spinal fusion device comprising a biodegradable polymer, a neutralizing agent, and one or more void spaces which has a mechanical strength suitable to withstand the great strain placed on spinal implants. In instances where the strength of the fusion device must be enhanced to support great mechanical loads, Applicants have provided additional features such as reinforcing fibers and polymer crosslinking, which neither Agrawal nor Ray mention. For these reasons, Ray in combination with Agrawal cannot make obvious claims 1, 3, 6, 11, 12, 16, 25, 30 and 33.

Brantigan

Claim 4 was rejected under 35 U.S.C. § 103(a) as obvious over Ray in view of Agrawal, and further in view of U.S. Patent No. 5,192,327 to Brantigan.

Brantigan describes a prosthetic device to integrate with and support vertebrae in a vertebral column (col. 1, line 64 to col. 2, line 43). The prosthetic device has to be biologically

acceptable but inert (col. 1, lines 64-65). Brantigan does not define the term "inert". However, one of ordinary skill in the art would recognize that the term "inert" refers to being chemically stable, e.g., the device would not degrade under physiological conditions when used in a human body. This notion is confirmed by the description at col. 2, lines 52-55 which states that the device provides "a permanent mechanically secure repair with living tissue." In contrast, the claimed device is formed of a polymer which degrades into acidic fragments upon hydrolysis. Likewise, Agrawal describes implantable devices formed from porous, biodegradable polymers. Therefore, there is no motivation to combine Brantigan and Agrawal. The combination of Ray and Brantigan alone would not produce the claimed device. Neither Ray nor Brantigan describe a pH buffering or neutralizing agent as required in the claimed device. Nor do they provide the motivation for one of ordinary skill in the art to make the claimed device having up to 75% a pH buffering or neutralizing agent. Accordingly, since there is no motivation to combine the describcings of Agrawal with either Ray or Brantigan, and the combination of Ray and Brantigan alone does not disclose the claimed invention, these references cannot render claim 4 obvious under 35 U.S.C. § 103.

Dunn

Claims 17-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray in view of Agrawal, and further in view of U.S. Patent No. 4,655,777 to Dunn.

Dunn describes a method of producing biodegradable prostheses and using the prostheses in medical applications (col. 3, lines 16-22). The prostheses were formed of calcium

aluminate (CaAl), β-Whitelockite (β-TCP) (col. 3, lines 20-22; col. 3, line 26 to col. 4, line 24) or CMC fibers (col. 8, line 55 to col. 9, line 32) and as reinforcing fibers (col. 10, line 55 to col. 11, line 23) and a biodegradable polymer (col. 11, line 24 to col. 12, line 31). Dunn does not describe or suggest making an interbody spinal fusion device. Nor does Dunn describe or describe a pH buffering or neutralizing agent or inclusion of grafting material for facilitating bone growth.

The combination of the reinforcing fibers from Dunn with the fusion cage described in Ray fails to achieve an interbody spinal fusion device comprising pH buffering or neutralizing agent as required in claims 17 and 18. Combination of the reinforcing fibers from Dunn with the implantable device describe in Agrawal fails to include the grafting material for facilitating bone growth. As argued above, there is no motivation to combine Agrawal with Ray, nor any reasonable expectation of success in the combination. Accordingly, the combination of Agrawal, Ray, and Dunn would not render claims 17 and 18 obvious under 35 U.S.C. § 103.

Suggs

Claims 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as obvious over Ray in view of Agrawal, and further in view of U.S. Patent No. 5,527,864 to Suggs et al.

Suggs describes the preparation of poly(propylene fumarate-co-ethylene oxide) (col. 2, lines 25-50). Suggs does not describe the formation of an interbody spinal fusion device comprising a bioresorbable polymer and a pH buffering or neutralizing agent.

Combining Suggs with the fusion cage described in Ray fails to produce an interbody spinal fusion device comprising pH buffering or neutralizing agent as required in claims 26, 28 and 29. Combining Suggs with the implantable device described in Agrawal fails to include grafting material for facilitating bone growth. As argued above, there is no motivation to combine Agrawal with Ray, nor any reasonable expectation of success in the combination. Accordingly, the combination of Agrawal, Ray, and Suggs would not render claims 26, 28 and 29 obvious under 35 U.S.C. § 103.

Double Patenting Rejection

Claims 27 and 31 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 6,241,771 to Gresser et al. Applicants direct the Examiner's attention to the Terminal Disclaimer filed on July 1, 2003.

Claim Objections

Claim 17 and 18 were objected to as being substantial duplicates of claims 19 and 20, respectively. Claim 19 has been canceled and claim 20 has been amended to overcome this objection. Claim 20 is substantially different than claim 18, as it recites that the reinforcing fibers are made of the buffering or neutralizing agent, while claim 18 recites that the reinforcing fibers are made of the resorbable material. The Examiner's careful review of the claims is appreciated.

U.S.S.N. 09/785,593
Filed: February 16, 2001
AMENDMENT AND RESPONSE TO OFFICE ACTION

Allowance of claims 1, 4-8, 11-18, 20, 24-31 and 33 is respectfully solicited.

Respectfully submitted,

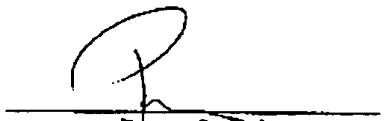
Patrea L. Pabst
Reg. No. 31,284

Date: February 17, 2004

HOLLAND & KNIGHT LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
(404) 817-8473
(404) 817-8588 (Fax)

Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, December 17, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



Patrea L. Pabst

Date: February 17, 2004

1463826_v1